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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,253	02/12/2004	Joseph Urban	PPS-104US	5398
23122	7590	08/04/2009		
RATNERPRESTIA P.O. BOX 980 VALLEY FORGE, PA 19482			EXAMINER LUBIN, VALERIE	
			ART UNIT 3626	PAPER NUMBER
			MAIL DATE 08/04/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/777,253	Applicant(s) URBAN ET AL.	
	Examiner VALERIE LUBIN	Art Unit 3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 17-21, 25-29, 34, 36 and 37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 17-21, 25-29, 34, 36 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/12/04, 6/29/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgements

1. Applicant's election without traverse of Group I, claims 1-8, 17-21, 25-29, 34, 36, 37 in the reply filed on 4/15/09 is acknowledged.

Claims 1-8, 17-21, 25-29, 34, 36, 37 are pending

For reference purposes, the document paper number is 20090721.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 1-8, and 17-21 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

4. Claims 1-8 and 17-21 are rejected under 35 U.S.C. §101 because the claimed invention is directed to non-statutory subject matter. Based on Supreme Court precedent (See also *Diamond v. Diehr*, 450 U.S. 175, 184 (1981); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972); *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1876)) and recent Federal Circuit decisions, a §101 process must (1) be tied to a particular machine or (2) transform underlying subject matter (such as an article or materials)

to a different state or thing. In addition, the tie to a particular apparatus, for example, cannot be mere extra-solution activity. See *In re Bilski*, 88 USPQ2d 1385 (Fed. Cir. 2008).

An example of a method claim that would not qualify as a statutory process would be a claim that recited purely mental steps.

To meet prong (1), the method step should positively recite the particular machine to which it is tied. This may be accomplished by having the claim positively recite the machine that accomplishes the method steps. Alternatively or to meet prong (2), the method step should positively recite identifying the material that is being changed to a different state or positively recite the subject matter that is being transformed.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 2, 3, 5-8, 17, 19, 20, 25, 26, 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Bodnick U.S. Pre-Grant Pub. 2002/0138302.

7. For claim 1, Bodnick teaches a method comprising the steps of: (a) storing identifiers (§ 28) and corresponding reminder protocols associated with the therapeutic regimen (§ 31); (b) receiving a communication of an identifier, a contact preference and a reminder

preference from a patient to receive the therapeutic regime, thereby activating the reminder protocol associated with the therapeutic regimen (§ 20, 21); (c) determining whether the patient corresponding to the received identifier requires a reminder of the therapeutic regimen according to the reminder protocol (§ 24); and (d) upon determining the patient corresponding to the received identifier requires a reminder of the therapeutic regimen according to the reminder protocol; reminding the patient of the therapeutic regimen in accordance with the contact preference and the reminder preference (§ 26).

With respect to limitation (d), Examiner notes that this is an optional limitation and according to the MPEP, "Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation" (MPEP 2106.II.C).

Claims 25 is rejected under the above analysis.

8. Claim 2 is rejected, as Bodnick teaches sending a reminder communication to at least one of a telephone number, an electronic mail address and a facsimile number (§ 6).

Claims 26 and 28 are rejected under the above analysis.

9. Claim 3 is rejected, as Bodnick recites authenticating the received identifier (§ 24).

10. Claim 5 is rejected as Bodnick recites storing the identifiers and corresponding reminder protocols in a database (§ 27).

11. Claim 6 is rejected, as Bodnick discloses receiving the identifier, the contact preference and the reminder preference via a telephone communication (§ 22, 24, 27).

12. Claim 7 is rejected as Bodnick recites determining whether the patient has communicated compliance to the therapeutic regimen (§ 38, 47).

13. For claim 8, Bodnick recites reminding the patient to take a medication according to a prescription, engage in a physical therapy, take a diagnostic test, take OTC medication, take a vitamin regimen, take a nutraceutical regimen, take a preventive medication, monitor a function, regulate or report a lifestyle function, or to activate or use a device (§ 26).

14. With respect to claim 17, Bodnick teaches a method comprising the steps of: (a) providing an identifier for distribution to a patient in connection with the therapeutic regimen (§ 20); (b) authorizing a reminder service (Abstract, § 6) to: (i) receive an identifier, a contact preference, and a reminder preference from the patient to receive the therapeutic regimen, thereby activating a reminder protocol associated with the therapeutic regimen (§ 20, 21); (ii) determine whether the patient corresponding to the received identifier requires a reminder of the therapeutic regimen according to the reminder protocol (§ 24); and (iii) upon determining the patient corresponding to the received identifier requires a reminder of the therapeutic regimen according to the reminder protocol, remind the patient of the therapeutic regimen in accordance with the contact preference and the reminder preference (§ 26).

With respect to limitation (iii), Examiner notes that this is an optional limitation and according to the MPEP, "Language that suggests or makes optional but does not require

steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation" (MPEP 2106.II.C).

Claim 20 is rejected under the analysis of claim 17.

15. Claim 19 is rejected, as Bodnick recites providing the identifier for distribution to the patient by a pharmacy (§ 20).

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bodnick U.S. Pre-Grant Pub. 2002/0138302.

18. With regards to claim 4, Bodnick recites forwarding an identifier to an accounting function of the reminder system (§ 24), and receiving from the system an authorization or approval status (Abstract). Bodnick does not specifically recite a clearing house, but Examiner takes Official Notice that clearing houses were old and well known in the art at the time the invention was made. It would therefore have been obvious to one of ordinary skill in

the art to substitute the accounting function of Bodnick with a clearing house, as both would have performed the same functions and yield predictable results.

19. Claims 18, 21, 27, 29, 34, 36, 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bodnick U.S. Pre-Grant Pub. 2002/0138302 in view of Brown U.S. Patent No. 5,307,263 further in view Knorr et al. Pre-Grant Pub. No. 2002/0077929.

20. With respect to claim 18, Bodnick recites providing an identifier for distribution to a patient in connection with a therapeutic regimen (§ 20).

Bodnick does not specifically recite (i) producing the therapeutic regimen and sending product information corresponding to the therapeutic regimen to a clearing house and (ii) receiving the identifier in connection with the therapeutic regimen from the clearing house; however, Brown recites producing medication dosage information and sending the information to a clearing house (Col. 12 lines 9, 10). Brown also discloses receiving an identifier in connection with the therapeutic regimen from the clearing house (Col. 12 lines 9-15). It would have been obvious to one of ordinary skill in the art to combine the teachings of Bodnick and Brown in order to control and secure the flow of information throughout the system.

Bodnick and Brown do not recite (iii) transferring the therapeutic regimen and corresponding identifier to one of a packager, a wholesaler, and a retailer; however, Knorr discloses transmitting order IDs to a vendor (Fig. 1 element 46). It would have been obvious to one of ordinary skill in the art to combine the teachings of Bodnick, Brown and Knorr in

order to facilitate communication among involved parties and to meet the patient or customer's demand as efficiently and quickly as possible.

21. For claims 21, 27, 29, 34, 36, 37, Examiner takes Official Notice that high frequency receivers/transmitters such as RFIDs were old and well known in the art at the time the invention was made. It would have been obvious to one of ordinary skill in the art to combine the prior art to include RFIDs in order to facilitate communication and data transmission/reception.

Conclusion

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to VALERIE LUBIN whose telephone number is (571)270-5295. The examiner can normally be reached on Monday-Friday 7:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher L. Gilligan can be reached on 571-272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/V. L./

Examiner, Art Unit 3626

/C. Luke Gilligan/

Supervisory Patent Examiner, Art Unit 3626